

## **REMARKS**

### **Interview Summary**

Applicant thanks Examiner Gottschalk for granting a telephonic interview on August 25, 2010 with applicant's representatives Louis D. Lieto and Esther Kepplinger. The examiner provided helpful suggestions on how to potentially clarify the claimed invention.

### **I. CLAIM STATUS**

Claims 4, 9, 12-13, 16, 24, 26-29, 48-52, 54, and 56 are currently amended. Claims 1-3, 5, 7-8, 10-11, 14-15, 18-19, 31-47, and 53 are cancelled. Claims 58- 63 are new. The current amendments and new claim are supported by the specification and claims as originally filed. No new matter is introduced herein. Reconsideration of the application in view of the current claims is respectfully requested and further in view of the following Remarks.

The amendments to the claims are supported throughout the specification and do not introduce any new matter. For example citation is made to relevant portions of the corresponding US Publication no. US20020143563, as follows:

Claims 4, 16, 48-52: paragraphs 5, 34.

Claims 58-63: Figure 4 and paragraphs 86, 87.

Amendments to claims 9, 12-13, 24, 26-29, 54, and 56 correspond to those in their respective independent claims.

### **II. CLAIM REJECTIONS - 35 USC § 103**

The Examiner has rejected claims 4, 6, 8-10, 13, 14, 16-18, 20-30 and 48-52 under 35 USC 103(a) as allegedly being unpatentable over Stark et al. (US Pat. No. 6, 827, 670) in view of in view of McAlindon (US Pat. No. 7,251,609).

In order to establish a *prima facie* case of obviousness, the Examiner must demonstrate that the prior art (i) teaches or suggests every claim limitation, (ii) provides a motivation to combine (or modify) the teachings of the selected references, and (iii) provides a reasonable expectation of success. In re Vaeck, 947 F.2d 488,20 USPQ2d 1438 (Fed. Cir. 1991); MPEP § 2143. Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some

rational underpinning to support the legal conclusion of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)). This rejection is respectfully traversed since a prima facie case of obviousness has not been established for the following reasons.

Applicants submit that Stark does not disclose every element of the pending claims and that McAlindon is insufficient to cure the deficiencies of Stark.

In rejecting Claim 4 and its dependents, the Examiner stated the “challenge level” of Stark is a type of “compliance threshold.” (Office Action 4/29/2010, pg. 5). Applicants note that claim 4 has been amended solely for the purposes of clarity. Claim 4 now recites in part: “comparing the subject compliance information from said each subject in said group of subjects to the preferred compliance threshold to determine if action is needed for said each subject in said group of subjects.” This and other amendments to claim 4 make clear that the group of subjects in the current clinical trial are all compared to the same “compliance threshold.” Thus the “compliance threshold” is a common benchmark that each subject in a subject group is compared to. This is different than the individualized “challenge level” of Stark. Stark discloses the “challenge level” in the context of the disclosed “system for treating orthopedic injuries” (Abstract) by providing “a protocol for biological manipulation to be performed on a patient.” (Col. 3 ll. 40-41). Further, Stark discloses that the “challenge level” is “a description of the protocol difficulty level.” (Col. 12, ll. 64-67). “This level should rise in conjunction with injury recovery, but be moderated by safety considerations.” (Stark, Col. 12, ll. 64-67). The “challenge level” of Stark is not the same as the “compliance threshold” of claim 4 and its dependent because the “challenge level” is an individualized protocol level that varies in response to a patient’s performance during orthopedic rehabilitation (Col. 3 ll. 34-35, Fig. 15; Col. 13 ll. 30-47). In contrast the “compliance threshold” of claim 4 and its dependent is a common benchmark to which measurements of subject compliance from each subject in a group of subject participating in a current clinical trial are compared. As such the compliance threshold is not the same as the “challenge level” of Stark nor is not modified based on an individual subject’s performance as the “challenge level” is in Stark. Therefore Stark does not disclose every element of claims 4 or its dependents.

Furthermore, to modify the “challenge level” of Stark to act in the manner of the claimed compliance threshold would render the “challenge level” of Stark unsatisfactory for its intended purpose because the “challenge level” could no longer be used on an individual basis as a protocol difficulty level that could be modified to progress over time to rehabilitate an orthopedic injury. (Col. 13 ll. 30-47). “If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” MPEP 2143.01(v) citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Applicants submit that modification

of the “challenge level” as suggested by the Examiner would render it unsatisfactory for its intended purpose of keeping “the patient challenged, strengthening faster, and on the road to recovery sooner.” (Stark, Col. 13 ll. 28-29).

McAlindon fails to cure the deficiencies of Stark as it fails to disclose all of the elements of pending claim 4 or its dependents, such as the element of a “compliance threshold.” Therefore a *prima facie* case for obviousness has not been established over claim 4 or its dependents.

In rejecting claim 16 (directed to a prediction rule), and its dependents, the Examiner also relied on Stark in view of McAlindon as set forth above. Specifically, the Examiner cites to Col. 13 ll. 38-39 of Stark as allegedly disclosing a predictive algorithm. (Office Action 4/29/2010, pg. 4). Further the Examiner states: “[n]ote the use of ‘low compliance track record’ as an input to the algorithm which determines if or by how much to adjust the ‘challenge level,’ i.e. a subject that performs poorly in the past would have this history taken into account with respect to future protocol adjustments.” (Office Action 4/29/2010, pg. 4). Applicants note that claim 16 has been amended to clarify the claims and now recites “comparing the subject compliance information from said each subject in said group of subjects to the prediction rule to determine if action is needed for said each subject in said group of subjects.” This and other amendments to claim 16 make clear that the group of subjects in the current clinical trial are all compared to the same “prediction rule.” Similar to the reasoning above regarding claim 4, the section of Stark cited by the Examiner makes clear that the “challenge level” progresses over time for each subject depending on the subject’s injuries (Col. 13 ll. 30-65). Thus, the “challenge level” of Stark is not the same as the prediction rule used in claim 16 because the challenge level is an individualized protocol level that varies in response to a patient’s performance during orthopedic rehabilitation (Col. 3 ll. 34-35, Fig. 15; Col. 13 ll. 30-47). Therefore, Stark does not disclose every element of claims 16 or its dependents.

Furthermore, to modify the “challenge level” of Stark to act in the manner of the claimed “prediction rule” would render the “challenge level” of Stark unsatisfactory for its intended purpose because the “challenge level” could no longer be used on an individual basis as a protocol difficulty level that could be modified to progress over time to rehabilitate an orthopedic injury. (Col. 13 ll. 30-47). “If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” MPEP 2143.01(v) citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Applicants submit that modification of the “challenge level” as suggested by the Examiner would render it unsatisfactory for its intended purpose of keeping “the patient challenged, strengthening faster, and on the road to recovery sooner.” (Stark, Col. 13 ll. 28-29).

McAlindon fails to cure the deficiencies of Stark as it fails to disclose all of the elements of pending claim 16 or its dependents, such as the element of a “prediction rule.” Therefore a *prima facie* case for obviousness has not been established over claim 16 or its dependents.

In rejecting claim 24 (directed to a decision rule), and its dependents, the Examiner also relied on Stark in view of McAlindon as set forth above. Applicants note that the Examiner did not explain in his rejection how the “decision rule” of claim 24 or its dependents was disclosed by the cited references. However, in order to advance prosecution Applicants have amended claim 24 and its dependents in a manner similar to the claims above. Applicants note that claim 24 has been amended to clarify the claims and now recites “comparing the subject compliance information from said each subject in said group of subjects to the decision rule on a portable electronic device or a computer to determine if corrective action is needed for said each subject in said group of subjects.” This and other amendments to claim 24 make clear that the group of subjects in the current clinical trial are all compared to the same “decision rule.” Similar to the reasoning above regarding claims 4, 16 and their dependents, the section of Stark cited by the Examiner makes clear that the “challenge level” progresses over time for each subject depending on the subject’s injuries (Col. 13 ll. 30-65). The “challenge level” of Stark is not the same as the “decision rule” used in claim 24 and its dependents because the challenge level is an individualized protocol level that varies in response to a patient’s performance during orthopedic rehabilitation (Col. 3 ll. 34-35, Fig. 15; Col. 13 ll. 30-47). Therefore Stark does not disclose every element of claims 24 or its dependents.

Furthermore, to modify the “challenge level” of Stark to act in the manner of the claimed “decision rule” would render the “challenge level” of Stark unsatisfactory for its intended purpose because the “challenge level” could no longer be used on an individual basis as a protocol difficulty level that could be modified to progress over time to rehabilitate an orthopedic injury. (Col. 13 ll. 30-47). “If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification,” MPEP 2143.01(v) *citing In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Applicants submit that modification of the “challenge level” as suggested by the Examiner would render it unsatisfactory for its intended purpose of keeping “the patient challenged, strengthening faster, and on the road to recovery sooner.” (Stark, Col. 13 ll. 28-29).

McAlindon fails to cure the deficiencies of Stark as it fails to disclose all of the elements of pending claim 24 or its dependents, such as the element of a “decision rule.” Therefore a *prima facie* case for obviousness has not been established over claim 24 or its dependents.

Applicants note that similar amendments have been made to the independent claims directed to a computer readable medium, claims 48-52. For the reasons stated above claims 48-52 and their dependents are not rendered obvious by the cited art.

Applicants also note that in the Examiner's Interview Summary of August 26, 2010, the Examiner stated: "[a]pplicants essentially argued that the Stark reference teaches compliance thresholds for an individual patient as opposed to the current invention which creates aggregate statistical compliance thresholds for comparison with current patient performance." Further the Examiner cited to Stark Col. 15 ll. 1-15. Applicants would like to point out that one aspect not addressed in the Examiner's interview summary is that the claimed comparison steps of the claims. For example, claim 4 comprises "comparing the subject compliance information from said each subject in said group of subjects to the preferred compliance threshold to determine if action is needed for said each subject in said group of subjects" (Emphasis added); claim 16 comprises "comparing the subject compliance information from said each subject in said group of subjects to the prediction rule to determine if action is needed for said each subject in said group of subjects" (Emphasis added); and claim 24 comprises "comparing the subject compliance information from said each subject in said group of subjects to the decision rule on a portable electronic device or a computer to determine if corrective action is needed for said each subject in said group of subjects." (Emphasis added). Applicants submit that Stark does not disclose these kinds of comparisons. Further, the section of Stark that the Examiner cited to in the Interview Summary (Stark Col. 15 ll. 1-15) is directed to measuring a patient's MVC (maximum voluntary contraction) of an uninjured limb or a lower value, such as 95% of the MVC of the uninjured limb and setting it as treatment goal. Further Stark states "preferably at least one of these values, i.e., measured MVC of the contralateral limb or proposed MVC goal, are compared to MVC values in the historic database." (Stark Col. 15 ll. 1-15). Applicants submit that the newly cited section of Stark does not disclose the comparison step of the claimed invention as the pending claims do not measure a patient's MVC as part of the "the subject compliance information from said each subject in said group of subjects". Further, the recently cited section of Stark is restricted to an individualized protocol level for each patient in question as it uses the information from the patient's uninjured limb in order to set the level.

In view of the amendments to the claims and the arguments above applicants respectfully request that the Examiner withdraw the rejection of claims 4, 6, 8-10, 13, 14, 16-18, 20-30 and 48-52 over the cited art.

The Examiner has also rejected claim 12 under 35 USC 103(a) as allegedly being unpatentable over "Stark in view of Drazen as applied to claim 8 above, and further in view of Smith (Smith, G., "Statistical

Reasoning.” Third edition. Ch. 15, pgs 619-667. Allyn and Bacon, a Division of Simon and Schuster, Inc., Needham Heights, MA. 1991, hereinafter Smith.)” (Office Action 4/29/2010, pg. 16).

Applicant’s submit that Drazen is no longer applicable art as the previously filed 1.131 affidavit overcame the Drazen reference. This was recognized by the Examiner in the most recent office action. (Office Action 4/29/2010, pg. 18). Applicant’s presume the basis of the Examiner’s rejection of claim 12 is in error and respectfully request the withdrawal of finality of the Office Action mailed on 4/29/2010 or issuance of claim 12.

### CONCLUSION

For the foregoing reasons, Applicant requests the Examiner allow claims 4, 6, 9, 12, 13, 16, 17, 20-30, 48-52 and 54-63 and advance the application to issuance.

### FEE AUTHORIZATION

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. **23-2415** (Docket No. 31886-705.201).

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By:

Respectfully submitted,



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